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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,678	05/01/2007	Kathryn E. Uhrich	01435.035US1	8472

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EXAMINER

ORWIG, KEVIN S

ART UNIT	PAPER NUMBER
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4161

MAIL DATE	DELIVERY MODE
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09/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,678	Applicant(s) UHRICH ET AL.	
	Examiner Kevin S. Orwig	Art Unit 4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,8-23,88,240 and 241 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1,2,8-23,88,240 and 241 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 2, and 8-23, drawn to a method for sequestering LDL.

Group II, claim 88, drawn to a method for treating a disease associated with pathological cells.

Group III, claims 240 and 241, drawn to a method for inhibiting atherosclerosis.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature among the inventions is the compound of chemical formula (I), which is not novel as evidenced by Uhrich *et al.* (International Publication No. WO 03/005959; Published Jan. 23, 2003; 2nd reference on the IDS submitted by applicant dated Nov. 17, 2006). Specifically, Uhrich *et al.* disclose compounds corresponding to formula (I) (abstract; pages 2-8, Figures 6, 10, and 11). Uhrich *et al.* teach the use of these compounds to sequester lipoproteins such as LDL (page 10, 4th paragraph, element (a)) by administering them to a patient in need of reducing the concentration of lipoproteins (page 10, end of 4th paragraph). Thus, both the common technical feature (the

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compounds of formula (I)) shared by the Groups and the method of Group I are disclosed by Uhrich *et al.* Because these elements cannot be considered novel, the common technical feature shared by the groups is not a special technical feature as defined under PCT Rule 13.2, Part I (b). Thus, the Groups do not share a common special technical feature and are subject to restriction.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

For Group I, the species are as follows:

- Compound of chemical formula (I) (claims 1, 2, and 8-23)
- Compound of chemical formula (II) (claim 18)

Should Group I be elected, applicant is required to specify a single chemical structure corresponding to formula (I), with defined A, X, Y, Z, and R₁ groups (a species for example is methyl, not alkyl), and a single chemical structure corresponding to formula (II), with defined A, X, Y, Z, and R₅ and R₆ groups and provide a single value for each of a and x where applicable.

For Group II, the species are as follows:

- Compound of chemical formula (I) (claim 88)

Should Group II be elected, applicant is required to specify a single chemical structure corresponding to formula (I), with defined A, X, Y, Z, and R₁ groups (a species for example is methyl, not alkyl).

For Group III, the species are as follows:

- Compound of chemical formula (I) (claims 240 and 241)

Should Group III be elected, applicant is required to specify a single chemical structure corresponding to formula (I), with defined A, X, Y, Z, and R₁ groups (a species for example is methyl, not alkyl).

4. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The claims are deemed to correspond to the species as set forth above. For Group I, claims 1, 2, and 8-23 are generic to the following disclosed patentably distinct species: Compound of chemical formulae (I) and (II). For Group II, claim 88 is generic to the following disclosed patentably distinct species: Compound of chemical formulae (I). For Group III, claims 240 and 241 are generic to the following disclosed patentably distinct species: Compound of chemical formulae (I).

7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

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corresponding special technical features for the following reasons: the compound of chemical formula (I) and the method for sequestering LDL (Group I) are anticipated by Uhrich *et al.* as set forth in paragraph 2 above.

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

9. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached Monday-Friday 8:00 am-5:00

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pm at (571)272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/Patrick J. Nolan/

Supervisory Patent Examiner, Art Unit 4161